REMARKS/ARGUMENTS

Claims 1-15, and 21-25 remain pending in this application. Claims 16-20 have been canceled, and new claims 21-25 have been added. Claims 1-6, 8, and 10-13 have been amended. Insofar as the total number of claims does not exceed 20 and the number of independent claims does not exceed 3, no additional fee is required. These amendments have been made for purposes of expediting prosecution and the Applicants reserve the right to pursue the full scope of the original claims in a continuation application.

Applicant has amended claim 1 to cover a method for treating or preventing stress induced respiratory disorders selected from the group consisting of exercise induced pulmonary hemorrhage, respiratory disease complex resulting from shipment or crowding, and upper respiratory infections accompanying stress. Support for this amendment can be found in the specification at page 9, lines 9-17, and page 10, lines 9-10 and 15-18.

The specification has been amended to update the status of U.S. Application 08/685,052.

A supplemental IDS submitting complete copies of the Erickson and Baker, et al. references is submitted herewith, along with the fee of $180.00.

The term "stress induced respiratory disorder" is recognized in the art.

The Examiner rejected original claims 1-20 under 35 U.S.C. 112, second paragraph, as being indefinite arguing that it is unclear what the term "stress induced respiratory disorder" means or encompasses. Applicants respectfully transverse this rejection.

Contrary to the Examiner's assertion, the term "stress induced respiratory disorder" is a recognized term in the field of veterinary animal health with a definite meaning. Specifically, those in the field of veterinary animal health recognize "stress induced respiratory

disorder" as encompassing "steadily decreasing lung capacity brought on by 'stress induced' elements." They further recognize that "stress induced" elements exclude pathogenic disorders and encompass exercise and elements outside of the animal, such as other animals and transportation.

Applicants submit herewith the declaration of Dr. Howard Erickson, entitled "Declaration I of Howard Erickson," ("Erickson I") and of Dr. James J. Sheldon, entitled "Declaration I of James J. Sheldon," ("Sheldon I") as evidence that the term "stress induced respiratory disorder" has a recognized and definite meaning the art. Both Dr. Erickson and Dr. Sheldon are skilled in the art of veterinary animal healthcare and familiar with the terms utilized therein (Erickson I, ¶¶ 1-6, Sheldon I, ¶¶ 1-5). Drs. Erickson and Sheldon indicate that the term "stress induced respiratory disorder" is recognized in the art as having the meaning set forth above (Erickson I, ¶¶ 8-10, Sheldon I, ¶¶ 7-9). In view of the forgoing evidence, Applicants submit it would be clear to one of ordinary skill in the art what "stress induced respiratory disorder" means and encompasses. Thus, Applicants respectfully request removal of the rejection under §112, second paragraph.

All claims are enabled by the specification.

The Examiner rejected original claims 1-20 under 35 U.S.C. 112, first paragraph, arguing the specification is not enabling for the claimed method of treating stress induced respiratory disorders to the extent that term encompasses exercise induced pulmonary hemorrhage (EIPH) or like disorders. Specifically, the Examiner argued that there is no evidence that the invention could be successfully used to treat EIPH. Applicants submit that the specification would enable one of ordinary skill in the art to practice the full breadth of the claimed invention and respectfully traverse the Examiner's rejection.

Applicants submit herewith the declaration of Dr. Howard Erickson, entitled "Declaration II of Howard Erickson," ("Erickson II"), who has utilized Ig compositions to successfully treat EIPH (Erickson II, ¶¶ 7-9). Dr. Erickson states that he has statistically significant, documented evidence that the administration of Ig compositions can be used as an effective treatment for EIPH (Erickson II, ¶¶ 7, 10), and provides a summary of such evidence (Erickson II, ¶¶ 8, 9).

In addition, Applicants submit the declaration of Dr. James J. Sheldon, entitled "Declaration II of James J. Sheldon," ("Sheldon II"). Dr. Sheldon states that he has documented evidence that the administration of Ig compositions can be used as an effective treatment for stress induced respiratory disorders in cattle (Sheldon II, ¶¶ 6, 10) and provides a summary of such evidence (Sheldon II, ¶¶ 7-9).

In view of the foregoing, Applicants submit that the specification of the present application would enable one skilled in the art to use Ig compositions for the treatment of EIPH and the full range of stress induced respiratory disorders claimed in the above-referenced Application without undue experimentation. As a result, Applicants respectfully submit that the specification enables the full breadth of the claims and request removal of the rejection under 35 U.S.C. 112, first paragraph.

The references cited by the Examiner are not anticipatory.

The Examiner rejected original claim 1 under 35 U.S.C. 102(b) as being anticipated by Levinson et al., Van Wye et al., and Hemming et al. The Applicants respectfully transverse these rejections.

Levinson et al. is directed to the use of Ig compositions to treat steroid dependent asthma. In view of Applicant's amendment to claim 1, the Examiner's rejection is now moot. In

view of the foregoing, Applicants respectfully request removal of the rejection over Levinson et al.

Van Wye et al. is directed to the use of hyperimmune globulin to treat pulmonary PA infection in cystic fibrosis patients. Hemming et al. is directed to the treatment of RSV with hyperimmune globulin. In view of Applicant's amendment to claim 1, the Examiner's rejections are now moot. In view of the foregoing, Applicants respectfully request removal of the rejections over Van Wye et al. and Hemming et al.

The Examiner has rejected claim 1 under 35 U.S.C. 102(a) as being anticipated by Ragland et al. Applicants respectfully submit that the Ragland et al. reference is not prior art under 102(a), insofar as Ragland et al. derived their knowledge of the claimed invention from the inventors of the present invention, as stated in the declaration of co-inventor William G. Skelly, submitted herewith. As a result, Applicants respectfully request removal of the rejection over Ragland et al.

The Examiner has indicated that Applicant's claim of priority extends only to parent application 08/685,052 and not to parent application 08/349,010. Applicants submit that they are able to overcome the Examiner's rejections without relying on the filing date of parent application 08/349,010. Thus, consideration of Applicant's claim of priority is unnecessary at this time. However, Applicants reserve the right to assert and establish their right to the priority claim in the future.

Attached hereto is a marked-up version of the changes made to the Specification and Claims by the current amendment. The attached page is captioned "Version With Markings to Show Changes Made".

In view of the foregoing amendments and remarks, it is respectfully submitted that the claims are now in condition for allowance and eventual issuance. Such action is respectfully requested. Should the Examiner have any further questions or comments which need be addressed in order to obtain allowance, he is invited to contact the undersigned attorney at the number listed below.

Acknowledgement of receipt is respectfully requested.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Specification:

Paragraph beginning at page 1, line 2 has been amended as follows:

This application is a Continuation of U.S. Patent Application Serial No. 08/685,052, filed July 23, 1996, now abandoned, which is a Continuation-in-Part of U.S. Patent Application Serial No. 08/349,010, filed December 2, 1994, which is now issued as U.S. Patent No. 5,548,066, both of which are hereby incorporated herein by reference.

In the Claims:

Claims 16-20 have been canceled.

New Claims 21-25 have been added as follows:

21. (New) A method according to claim 1, wherein said stress induced respiratory disorder is respiratory complex caused by transportation or crowding.

22. (New) A method according to claim 21, wherein said respiratory complex is bovine respiratory complex.

23. (New) A method according to claim 21, wherein said respiratory complex is porcine respiratory complex.

24. (New) A method according to claim 1, wherein said stress induced respiratory disorder is upper respiratory infection caused by shipping or transport.

25. (New) A method according to claim 24, wherein said patient is a horse suffering from upper respiratory infection.

Please amend claims 1-7, 8 and 10-13 as follows:

1. (Amended) A method of treating ~~a patient suffering from~~or preventing a stress induced respiratory disorder in a patient, wherein said method comprises administering to said

patient an immunoglobulin composition comprising immunoglobulins, and wherein said stress induced respiratory disorder is selected from the group consisting of exercise induced pulmonary hemorrhage, respiratory disease complex resulting from shipment or crowding, and upper respiratory infections accompanying stress.

2. (Amended) A method according to claim 1, wherein ~~said patient~~stress induced respiratory disorder is ~~a horse suffering from~~ exercise induced pulmonary hemorrhage.

3. (Amended) A method in accordance with claim ~~2,~~1, wherein said immunoglobulin composition is administered ~~between~~ three ~~and~~to five times within a period ranging ~~between~~from six to ten days.

4. (Amended) A method in accordance with claim ~~2,~~1, wherein said immunoglobulin composition is administered every seven to ten days.

5. (Amended) A method in accordance with claim ~~2,~~1, wherein said immunoglobulin composition is administered in doses ~~of~~ranging ~~between~~from 5 ~~and~~to 20 ml of said immunoglobulin composition.

6. (Amended) A method in accordance with claim ~~2,~~1, wherein said immunoglobulin composition is administered by a mode selected from the group consisting of intratracheal administration, vapor inhalation and/or intravenous administration.

8. (Amended) A method in accordance with claim 6, wherein said immunoglobulin composition is administered by ~~intravenous injection~~vapor inhalation.

10. (Amended) A method in accordance with claim ~~9,~~8, wherein said immunoglobulin composition is administered ~~between~~ three ~~and~~to five times within a period ranging ~~between~~from six ~~and~~to ten days.

11. (Amended) A method in accordance with claim ~~9~~,8, wherein said immunoglobulin composition is administered every seven to ten days.

12. (Amended) A method in accordance with claim ~~9~~,8, wherein said immunoglobulin composition is administered in doses ~~of~~ranging ~~between~~from 5 ~~and~~to 20 ml of said immunoglobulin composition.

13. (Amended) A method in accordance with claim ~~2~~,1, wherein said immunoglobulin composition comprises a concentrated amount of one or more gamma globulins selected from the group consisting of IgG, IgG_t, IgM, IgA, IgE, IgD and/or mixtures thereof.